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February 2, 2021

**VIA ECF**

Honorable Kevin McNulty, U.S.D.J.  
United States District Court, District of New Jersey  
United States Post Office & Courthouse  
Federal Square, Room 369  
Newark, NJ 07101

Re: *United States ex rel. Silbersher v. Janssen Biotech, et al.*, Civil  
Action No. No. 19-12107(KM-JBC)

Dear Judge McNulty:

We represent the Defendants in this case along with co-counsel from Sidley Austin LLP, Walsh Pizzi O'Reilly Falanga LLP, and White & Case LLP. We write in response to Relator's Notice of Supplemental Authority, Dkt. 110, submitted December 21, 2020. In his letter, Relator requests the Court to forgo oral argument and deny Defendants' joint motion to dismiss on the basis of a recently issued decision by Chief Magistrate Judge Joseph Spero in one of Relator's other, pending *qui tam* lawsuits, see *Silbersher v. Allergan, Inc.*, 2020 WL 7319407 (N.D. Cal. Dec. 11, 2020). The Court should reject Relator's request for procedural and substantive reasons.

Procedurally, Relator's correspondence is inappropriate as there is no pending motion to address, let alone deny, as the Court administratively terminated Defendants' joint motion to dismiss on June 22, 2020. *See* Dkt. 109. The Court's June 22 order recognized that further action in this case awaits resolution of class leadership issues and the filing of an amended complaint in the related antitrust actions, Case Nos. 19-14146 & 19-14291.<sup>1</sup> Per the Court's order, Defendants' joint motion is to be restored by "letter notification in coordination with the deadline to answer or otherwise move with respect to Plaintiffs' Complaints" in the antitrust actions. *See* Dkt. 109. As this letter exchange suggests, given the passage of time, Defendants respectfully submit that, when Defendants' motion to dismiss is restored, the parties should be permitted to file new

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<sup>1</sup> As the Court is aware, Defendants recently requested a conference with the Court to discuss the status of the antitrust and *qui tam* cases. *See* Dkt. 111.

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briefs addressing any developments in the law since the briefing on Defendants' motion was completed.

Relator's request also lacks substantive merit, for at least four reasons.

*First*, while the trio of *Silbersher* cases are “nearly identical” in legal theory, the defendants' motions to dismiss were not identical, and the subsequent judicial opinions reflect those differences. For instance, the *Allergan* opinion's public-disclosure-bar analysis omitted several issues raised in Defendants' motion to dismiss here, including:

- the Government's unique role in an *inter partes* review (“IPR”) that renders it a party to the action, thereby triggering romanette (i) of the public disclosure bar. *See* Motion to Dismiss, Dkt. 79-1, at 11; Reply Brief, Dkt. 99, at 2.
- the differences between romanettes (i) and (ii) that, when read harmoniously, give effect to the whole statute. *See* Dkt. 99 at 3–4.
- the distinct interests served by PACER and PAIR that warrant differing treatment under the public disclosure bar. *Id.* at 4.

Each point reinforces that IPRs and PAIR are qualifying Federal hearings and reports in ways *Allergan* simply did not address. Critically, undergirding the *Allergan* court's analysis was a mistaken reliance on legislative history—specifically, a House report that did not pertain to the False Claims Act's 2010 amendments, but instead concerned a bill that Congress never even passed. *See* 2020 WL 7319407, at \*8 (citing Rept. of Committee on the Judiciary, False Claims Correction Act of 2009, H.R. 1788, H.R. Rep. No. 111-97 (2009)).

And while it is true that the *Allergan* court did not apply “a heightened specific intent standard applicable to inequitable conduct” in the FCA context, Dkt. 110, the decision simply did not address at all the different standards for a False Claims Act violation and inequitable conduct. In contrast, the appropriate standard by which to judge the underlying alleged fraud is a central pillar of Defendants' joint motion to dismiss—to allow Relator to avoid “plead[ing] ... a claim for inequitable conduct” as required by established patent and antitrust law would permit him to “us[e] the FCA to create liability for invalidated patents where none would otherwise exist.” Dkt. 79-1 at 32.

*Second*, the *Allergan* court's analysis of the merits of Relator's claims was heavily constrained by Ninth Circuit precedent that does not apply in this case. Defendants' joint motion addresses the insufficiency of Relator's theory of falsity and allegations of materiality under the law of this Circuit. Dkt. 79-1, 23–32, Dkt. 99 at 8–15. As Defendants explained in their joint reply brief, Relator seeks to use a Ninth Circuit decision to expand the theory of promissory fraud in ways not recognized by this Circuit, nor indeed by any other circuit. Dkt. 99 (citing *U.S. ex rel. Campie*

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*v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017)). While the *Allergan* court was bound by *Campie*, and applied *Campie*'s logic in an unduly sweeping manner, this Court is not so bound—by either *Campie* itself or any subsequent misapplication—and is further entitled to judge the merits of Relator's claim under Third Circuit precedent.

*Third*, in light of the complexity, novelty, and importance of the issues surrounding the application of the public disclosure bar, Chief Magistrate Judge Spero has granted a motion filed by the *Allergan* defendants to certify the case for immediate appellate review pursuant to 28 U.S.C. § 1292(b), and stayed further proceedings while the matter proceeds in the Ninth Circuit. *See* Order Granting Motion to Certify Order for Immediate Appeal and for Stay, *Allergan*, No. 3:18-cv-3018 (N.D. Cal. Jan. 28, 2021), Dkt. 147 (Ex. A). Should the Ninth Circuit accept the appeal, its analysis could call into question the persuasive value of the Magistrate Judge's reasoning.

*Lastly*, Relator short-changes the considered opinion of District Court Judge James Donato in the *Valeant* case—another one of Silbersher's three “nearly identical FCA action[s],” including this one—who reached starkly opposite conclusions than the *Allergan* court. Dkt. 110; *see Silbersher v. Valeant Pharms. Int'l, Inc.*, 445 F. Supp. 3d 393 (N.D. Cal. 2020) (attached as Ex. B), *appeal filed* (9th Cir. Jun. 16, 2020). There, Judge Donato dismissed Relator's case as built upon “the foundation” of prior proceedings concerning the relevant patent. *Id.* at 399. Observing that Relator is “a far cry from the quintessential whistleblower plaintiff,” the court rejected the linchpin to Relator's case—that the 2010 amendments to the FCA were “a major sea change such that a qui tam action that would have been an opportunistic lawsuit under prior law is now a good case.” *Id.* at 402–03. Rather, the *Valeant* court concluded that “[t]he allegations ... about the obviousness of the '688 patent, and defendants' allegedly nefarious conduct in obtaining it, were all disclosed in the PTAB proceedings.” *Id.* at 404. The court further found that Relator procured those allegations from enumerated fora, rightly observing that romanette (ii) of the public disclosure bar “is not subject to the same government-party limitation” as romanette (i), and that PTAB proceedings constitute a federal hearing under romanette (ii). *Id.* at 405–06.

Predictably, Relator appealed Judge Donato's sound reasoning, and the Ninth Circuit is now considering the application of the public disclosure bar to certain patent-related proceedings and materials, as well as any other related issue it chooses to take up. *See Silbersher v. Valeant Pharms. Int'l, Inc.*, Case No. 20-16176 (9th Cir.). The Ninth Circuit's decision in this regard could undoubtedly affect the value of the *Allergan* analysis.

In short, there is no reason for this Court to wholesale adopt the *Allergan* opinion, ignore entirely the *Valeant* opinion, or preemptively deny Defendants' joint motion, all before that motion is even reinstated. Rather, Defendants respectfully request the Court consider Defendants' joint motion on its own terms and in due course. As indicated at the outset, Defendants would be pleased to submit new or supplemental briefing on recent case developments, including the *Allergan* or *Valeant* opinions or any subsequent Ninth Circuit decision, in support of their joint motion to dismiss Relator's complaint.

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Respectfully yours,

*s/ Jeffrey J. Greenbaum*

JEFFREY J. GREENBAUM

cc: All Counsel of Record (via ECF)  
Honorable James B. Clark III, U.S.M.J. (via ECF)